

657—10.15 (124,155A) Security requirements. All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a person has provided effective controls against diversion, the board shall use the security requirements set forth in these rules as standards for the physical security controls and operating procedures necessary to prevent diversion.

10.15(1) *Physical security.* Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operation. A registrant shall periodically review and adjust security measures based on rescheduling of substances or changes in the quantity of substances in the possession of the registrant.

a. Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

b. Controlled substances listed in Schedules II through V may be stored in a securely locked, substantially constructed cabinet. However, pharmacies and hospitals may disperse these substances throughout the stock of noncontrolled substances in a manner so as to obstruct the theft or diversion of the controlled substances.

c. Controlled substances collected via an authorized collection program for the purpose of disposal shall be stored pursuant to federal regulations, which can be found at http://deادiversion.usdoj.gov/drug_disposal/.

10.15(2) *Factors in evaluating physical security systems.* In evaluating the overall security system of a registrant or applicant necessary to maintain effective controls against theft or diversion of controlled substances, the board may consider any of the following factors it deems relevant to the need for strict compliance with the requirements of this rule:

a. The type of activity conducted;

b. The type, form, and quantity of controlled substances handled;

c. The location of the premises and the relationship such location bears to security needs;

d. The type of building construction comprising the facility and the general characteristics of the building or buildings;

e. The type of vault, safe, and secure enclosures available;

f. The type of closures on vaults, safes, and secure enclosures;

g. The adequacy of key control systems or combination lock control systems;

h. The adequacy of electric detection and alarm systems, if any;

i. The adequacy of supervision over employees having access to controlled substances, to storage areas, or to manufacturing areas;

j. The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

k. The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;

l. The availability of local police protection or of the registrant's or applicant's security personnel; and

m. The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances.

10.15(3) *Manufacturing and compounding storage areas.* Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in any schedule shall be stored pursuant to federal laws and regulations.